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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,493	03/22/2002	Solomon B. Margolin	183-109(US)	9283

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John H Crozier  
1934 Huntington Turnpike  
Trumbull, CT 06611-5116

EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/646,493

**Applicant(s)**

MARGOLIN, SOLOMON B.

**Examiner**

Kevin E. Weddington

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☒ Claim(s) 16-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Claims 1-18 are presented for examination.

Applicant's election filed September 3, 2004 in response to the restriction requirement of August 17, 2004 had been received and entered. The applicant elected the invention described in claims 10-18 (Group II) with traverse.

Applicant's traverse of the restriction requirement is not deemed persuasive for reasons set forth in the Office action dated August 17, 2004 since the composition of Group I can be used differently than the method of Group II. Therefore, the restriction requirement is hereby made Final.

Claims 1-9 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

### ***Claim Objections***

Claims 16-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pirfenidone (5-methyl-1-phenyl-2-(1H)-pyridone), does not reasonably provide enablement for other 2-(1H)

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pyridones. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In the regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

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The claimed invention relates to a method of treating bacteria, fungi, and/or viruses on the surface of, or within, the layers of the dermis of skin, ears, fingernails, toenails, or hoofs of mammalian species, comprising: applying to said surface or layers a pharmaceutical substance including an effective amount of one or more 2-(1H) pyridone compound(s).

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for 2-(1H) pyridone compound(s) to treat bacteria, fungi, and/or viruses on the surface of, or within, the layers of the dermis skin, ears, fingernails, toenails, or hoofs of mammalian species.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of pirfenidone.

The quantity of experimentation necessary

Applicant have failed to provide guidance as to how the other 2-(1H) pyridone compounds disclosed in claim 1 is effect in treating bacteria, fungi, and/or viruses on the surface of, or within, the layers of the dermis of skin, ears, fingernails, toenails, or hoofs of mammalian species. The level of experimentation needed to determine the other 2-(1H) pyridone compounds would be able to treat bacteria, fungi, and/or viruses is undue. Therefore,

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undue experimentation would be required to practice the invention it is claimed in its current scope.

Claims 10-15 are not allowed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, the phrase "including" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 14 is rendered indefinite and vague by the use of the phrase "etc." in line 32. What is meant by this phrase? Are there other heterocyclic groups used for the "A" substituent.

The remaining claims 11-13 and 15 are rendered indefinite to the extent that they incorporate the above terminology.

Claims 10-15 are not allowed.

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lohaus et al. (3,883,545).

Lohaus et al. teach 1-hydroxy-2-pyridones, same as (2-(1H)-pyridone compounds), exhibit antimycotic properties (See the abstract). Note particularly column 4, lines 62-68 and column 5, lines 1-5 states the pyridone compounds are effective against dermatomycoses and dermatophytes (a fungus pathogenic for the skin) note the fungi that are eradicated by the pyridone compounds. Column 7, lines 6-20 shows the instant 2-(1H) pyridone compounds are administered in the form of solutions (aqueous dispersion), creams, ointments, powders or sprays, which are applied superficially to the affected areas of the skin. Also note in column 7, lines 15-17 states the percentage of active ingredients (2-(1H) pyridone compounds) is between 0.2 and 2 percent and applicant's claim 13 percent of the active ingredient is 2 to 10 percent which overlaps the cited reference. Clearly, the cited reference anticipates the applicant's instant invention; therefore, the instant invention is unpatentable.

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Claims 10-13 are not allowed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohaus et al. (3,883,545).

Lohaus et al. were discussed above supra for the use of 1-hydroxy-2-pyridones (2-(1H) pyridone compounds) to treat fungi pathogens of the skin.

The instant invention differs from the cited reference in that the cited reference does not teach or disclose the preferred 2-(1H) pyridone compounds of applicant's claims 14 and 15, wherein the "A" is phenyl, thienyl, or other aryl groups. However, one skilled in the art would have expected the applicant's instant 2-(1H) pyridone compounds would possess the same activity as the 1-hydroxy-2-pyridones of the cited reference since the cited reference structure of the 1-hydroxy-2-pyridones and the structure of the instant 2-(1H) pyridone compounds of claim 14 have the same piperidine ring core structure. Therefore, it would have been obvious for the skilled artisan to administer the instant 2-(1H)



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pyridone compounds of the instant invention to a patient for the treatment of fungi in the absence of evidence to the contrary.

Claims 14 and 15 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

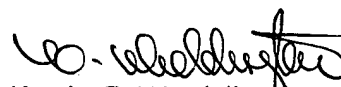
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "K. Weddington", with a stylized flourish at the end.

Kevin E. Weddington

Primary Examiner

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K. Weddington

January 3, 2005